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Title page

Thermal suit connected to a forced-air warming unit for preventing intraoperative hypothermia: a randomised controlled trial

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Background: Inadvertent intraoperative hypothermia is a common occurrence in surgical patients. A thermal suit is an option for passive insulation. However, active warming is known to be more effective. Therefore, we hypothesised a forced-air warming unit connected to the thermal suit is superior to a commercial forced-air warming blanket and a warming mattress in breast cancer surgery.

Methods: Forty patients were randomised to this prospective, clinical trial to wear either the thermal suit or conventional hospital clothes under general anaesthesia. The Thermal suit group had a forced-air warming unit set to 38 °C and connected to the legs of the suit. The Hospital clothes group had a lower body blanket set to 38 °C and a warming mattress set to 37 °C. Core temperature was measured with zero-heat-flux sensor. The primary outcome was core temperature on admission to the recovery room.

Results: There was no difference in mean core temperatures at anaesthetic induction (P=0.4) or on admission to the recovery room (P=0.07). One patient in the Thermal suit group (5%) vs. six patients in the Hospital clothes group (32%) suffered from intraoperative hypothermia (P=0.04, 95% CI 1.9 to 49%). Mean skin temperatures were higher in the Thermal suit group during anaesthesia. No burns or skin irritations were reported. Two patients in the Thermal suit group sweated.

Conclusions: A thermal suit connected to a forced-air warming unit was not superior to a commercial forced-air warming blanket, although the incidence of intraoperative hypothermia was lower in patients treated with a thermal suit.

Editorial comments: The advantages of perioperative forced-air warming include both a reduction in postoperative complications and improved patient comfort. However, the present randomised study demonstrates that forced-air warming by means of a thermal suit probably is not superior to using a conventional forced-air warming blanket.

Introduction

Inadvertent perioperative hypothermia (IPH), defined as a core temperature below 36 °C[1], is common in patients undergoing surgery. Hypothermia can lead to several adverse effects, such as decreased drug metabolism[2], impaired coagulation[3], increased blood loss[4] and wound infections[5], increased risk of myocardial ischemia[6] and delayed recovery[7]. In addition, feeling cold and experiencing shivering postoperatively are uncomfortable and distressing for the patient.

Many active and passive warming techniques are used to prevent IPH. However, active warming has been reported to be more effective than passive insulation[8]. Despite the effective warming techniques currently in use, as many as half of all surgical patients still experience hypothermia[9]. The most efficient method for preventing IPH is preoperative warming[10], but it is not always available. Hence, multiple warming methods are often applied during surgery. Using several warming methods for one particular patient, however, increases costs and waste and the workload of healthcare professionals.

One option for passive perioperative warming of patients is a thermal insulating suit that is worn instead of hospital cotton clothes. The jumpsuit is made of a three-layer laminate fabric composed of an outer layer of woven smooth microfiber, a waterproof, breathable fabric middle layer, and a

microfleece inner layer. The thermal suit can be used for various surgical procedures due to multiple zippers. The suit is reusable and can be washed up to 80 times or until 180 weeks, if the number of washes cannot be calculated.

The benefit of a thermal suit in preventing IPH is unclear since recently published studies show conflicting results[11, 12]. To optimise the feasibility of the suit, the manufacturer has developed an adapter that leads forced warm air to the inside of the suit.

We are unaware of any previous studies that have examined the thermal suit connected to a forced-air warming (FAW) unit in clinical practice. We hypothesised that this new method is superior to the conventional intraoperative warming method, comprising a commercial lower body FAW blanket and a warming mattress. We chose breast cancer patients as a study group because in unilateral breast surgery all circumstances are easily standardised, allowing a strictly controlled study of warming methods. The primary aim of this clinical trial was to investigate the effectiveness of the thermal suit connected to a FAW unit in preventing IPH in patients under general anaesthesia. Secondary aims were to evaluate the usability, compliance and related costs of this new method.

Methods

This prospective, randomised study was approved by the Ethics Committee of Tampere University Hospital, Tampere, Finland (R17137) on 12th December 2017, and registered at ClinicalTrials.gov on 2nd February 2018 (Code NCT03420924). Written informed consent was obtained from all patients. Valvira (the National Supervisory Authority for Welfare and Health in Finland) was notified at the beginning of the study.

The study population consisted of females who were scheduled for primary, unilateral mastectomy or resection of the breast with or without lymphadenectomy of the axilla due to breast cancer. The inclusion criteria were age 20 to 90 years, American Society of Anesthesiologists (ASA) physical status I-III classification and body mass index (BMI) 25 to 40[13]. The exclusion criteria were insufficient knowledge of the Finnish language or any other impediment that prevented the participants from giving informed consent. During the preoperative visit, participants were assessed for eligibility and recruited to the study by an anaesthesiologist (S-LL). The patients were then randomised to this parallel, 1:1 allocated study. In the morning of the surgery, the attending nurse opened the sealed randomisation envelope and the patients were dressed in either a thermal suit (T-Balance®, Telespro Finland Ltd., Kuopio, Finland; Thermal suit group), or conventional hospital cotton clothes (Hospital clothes group).

Patients did not receive any premedication or active prewarming. Non-invasive blood pressure, electrocardiography and pulse oximetry monitoring was initiated before anaesthetic induction. General anaesthesia was induced and maintained with target-controlled infusions (TCI, Asena™ PK, Alaris Medical Systems, Basingstoke, UK). Propofol was administered with the Schnider model and remifentanil with the Minto model. State Entropy (GE Healthcare, Helsinki, Finland) values were kept between 40 and 60. A laryngeal mask (i-gel®, Intersurgical Ltd, Wokingham, Berkshire, United Kingdom) was used to secure the airway. Inspiratory oxygen fraction was 0.5 at a fresh gas flow of 2 l min^{-1}. The end-tidal partial pressure of carbon dioxide was kept between 4.5 kPa and 5.0 kPa.

All patients received FAW (3M™ Bair Hugger™, Arizant Healthcare, Eden Prairie, MN, USA) intraoperatively. The nozzle of the FAW (Warming Unit model 750) was connected to the legs of the T-Balance thermal suit using a Y-piece adapter newly developed for the thermal suit system (Fig 1). The Hospital clothes group had a lower body FAW blanket (model 52500). In both groups, the FAW was turned on at 38 °C immediately after surgical draping. The Hospital clothes group also had a warming mattress (Astopad®, Armstrong Medical, Coleraine, Northern Ireland) set at 37 °C from the beginning. Intravenous fluids were taken from the warming cabinet (Heraeus Function Line B12, Thermo Fischer Scientific Inc., Hanau, Germany) set at 36.5 °C, but the fluids were not actively warmed perioperatively.

Hypothermia was defined as a core temperature ≤ 35.9 °C[1]. If hypothermia occurred, the warming mattress was set to 39 °C and intravenous fluids were actively warmed at 38 °C (BW 585M, Biegler GmbH, Mauerbach, Austria) in both groups. For the Hospital clothes group, the FAW was set at 43 °C. If the core temperature exceeded 38 °C, active warming was discontinued.

If the patient felt cold postoperatively, a warm blanket or forced-air warming was initiated, depending on the decision of the nurse. Otherwise, postoperative active warming was not used.

Intra- and postoperatively, the core temperature ($Temp_{ZHF}$) was measured using a non-invasive Zero-heat-flux sensor (3M™ Bair Hugger™ Temperature Monitoring System, Arizant Healthcare, Eden Prairie, MN, USA) that was placed on the patients` lateral forehead before anaesthetic induction. During anaesthesia, the nasopharyngeal temperature ($Temp_{Naso}$; General purpose probe®, GE Healthcare, Helsinki, Finland) was used as the reference method. The probe was inserted to the depth of the distance between the nostril and the auditory canal. Preoperative core temperature was measured once from the eardrum (Genius™2 Tympanic Thermometer and Base, Covidien llc, Mansfield, MA, USA). Skin temperatures (Skin Temperature Probe®, GE Healthcare, Helsinki, Finland) were measured from the chest (t_{chest}), upper arm (t_{arm}), thigh (t_{thigh}) and leg (t_{leg})[14]. The core and skin temperatures were continuously recorded intraoperatively and for up to 1 hour postoperatively, and the data were saved every 10 minutes. Patients` characteristics and relevant perioperative data as well as temperatures were documented in a data collection file.

The primary outcome was the core temperature value on admission to the recovery room. Secondary outcomes were changes in the core and peripheral temperatures intraoperatively and

postoperatively, the level of satisfaction with the warming method of both patients and nurses and the costs of the warming methods used.

We aimed to detect a difference of 0.5 °C in mean core temperature between groups. Based on a previous study[15], a standard deviation of 0.5 °C was chosen. With an alpha error of 0.05 and a power of 80%, the sample size of 16 patients per group was calculated. To allow for dropouts, 20 patients were enrolled for each study group.

Statistical analysis was performed using SPSS Version 25.0. (IBM Corp: Armonk, NY). Normally distributed data are presented as mean (SD). The Shapiro-Wilk test of normality was used to confirm normal distribution of data. T-test was used for continuous data, Fisher`s exact test for binominal data and Spearman`s correlation for calculating statistical relationship. In order to evaluate the thermal redistribution, we applied Ramanathan`s formula[14], where four peripheral temperatures are used to calculate mean skin temperature (MST): $MST_R = 0.3 \times (t_{chest} + t_{arm}) + 0.2 \times (t_{thigh} + t_{leg})$.

A P-value of < 0.05 was considered statistically significant.

Results

The data were collected between February and July 2018. After screening 126 patients, forty patients were randomised either to the Thermal suit group (n=20) or the Hospital clothes group (n=20). One patient allocated to the Hospital clothes group was excluded from the final analysis due to missing data (Fig 2). Patients` characteristics and relevant perioperative data were similar between groups (Table 1). No patient was hypothermic on admission to the hospital or at anaesthetic induction. Time spent in the holding area varied and was longer in patients operated in the afternoon. General anaesthesia was induced 13 (4) minutes after admission to the OR in both groups and FAW was turned on 19 (4) and 20 (4) minutes after induction in the Thermal suit group and Hospital clothes group, respectively. During the first 40 min of surgery, $Temp_{Naso}$ was statistically lower than $Temp_{ZHF}$. Thereafter, both temperatures paralleled closely with each other until the end of anaesthesia, although $Temp_{Naso}$ remained 0.14 degrees lower.

After anaesthetic induction, the drop in mean core temperature was 0.8 (0.2) °C and 0.9 (0.3) °C in the Thermal suit and Hospital clothes groups, respectively (Fig 3). Intraoperatively, one patient in the Thermal suit group (5%) and six patients in the Hospital clothes group (32%) became hypothermic (P=0.04, 95% CI 1.9 to 49%). The lowest $Temp_{ZHF}$ was 35.5 °C in the Thermal suit group, and 35.4 °C in the Hospital clothes group. All seven patients were already hypothermic at the 30 min time point after induction. The mean duration of hypothermia in the six patients randomised to wear hospital clothes was 35 minutes (10 to 60 minutes), whereas the only Thermal suit group patient was hypothermic for 60 minutes, and her hypothermia lasted for the postoperative period of the treatment. All hypothermic patients in the Hospital clothes group regained normothermia during general anaesthesia. There was no inter-group difference in mean core temperatures on admission to the recovery room (primary outcome) (Table 2). All patients were normothermic except for one patient in the Thermal suit group.

Intraoperative skin temperatures are presented in Table 2. In the Hospital clothes group, the maximum values were measured from the leg and thigh. The mean skin temperatures (MST) were higher in the Thermal suit group (Fig 4). The differences in MST between groups were significant with the exception of the 10 minutes, 20 minutes and after 70 minutes time points. A longer time spent in the holding area did not correlate with higher MST on admission to the OR (r_S = -0.208).

Postoperatively, the mean $Temp_{ZHF}$ was 36.6 °C in the Thermal suit group and 36.7 °C in the Hospital clothes group (*P*=0.20) (Fig 3). In the Hospital clothes group, no patients were hypothermic. In the Thermal suit group, however, three patients had $Temp_{ZHF}$ below 36 °C for periods of between ten and sixty minutes, but they did not report feeling cold. In the recovery room, mean skin temperatures were similar between groups (Fig 4).

No tissue irritation or burns were reported by the patients or the medical staff. However, two patients in the Thermal suit group experienced sweating. In one case, sweating was noticed intraoperatively by the surgeon, and in another case postoperatively by a nurse. With the exception of one patient from each group and two nurses from the Hospital clothes group, patients and nursing staff were satisfied with the warming method. In total, the acquisition and operating costs per patient were 14.55 EUR (13.34 GBP) for the Thermal suit group and 11.53 EUR (10.57 GBP) for the Hospital clothes group.

Discussion

Our study evaluated a new method of forced warm air delivery and compared it with conventional intraoperative warming methods. The results showed a lower prevalence of intraoperative hypothermia and higher mean skin temperatures in the Thermal suit group compared with those of the Hospital clothes group. Still, the superiority of the thermal suit connected to a FAW unit over the standard warming method lacked evidence, since there was no difference in the mean core temperature of patients on admission to the recovery room.

The National Institute for Health and Care Excellence (NICE) clinical guideline recommends the core temperature to be over 36 °C perioperatively[1]. Because the disadvantages of hypothermia are well known, we strictly followed the NICE recommendation and active warming was enhanced when the core temperature dropped below 36 °C. As a result, all six hypothermic patients in the Hospital clothes group were normothermic by the end of anaesthesia. The commercial lower body FAW blanket with maximum set temperature was effective in warming up hypothermic patients, a finding also reported in a previous study by Röder and collegues[16]. By contrast, the medium set FAW together with maximal set warming mattress and on-line warmed intravenous fluids were insufficient to warm up the hypothermic patient in the Thermal suit group. The most obvious reason for the persistent hypothermia is the avoidance of the maximum set temperature of FAW. Another reason might be the insulation effect of the suit that prevented the external warming device, the warming mattress in our study, from reaching the patient through the multi-layered fabric of the Thermal suit. This "thermos phenomenon" was seen in our previous study[12] and also by Brodshaug and co-workers[17]. In their study, the re-establishment of normothermia took a significantly longer time in the Thermal suit group.

To the best of our knowledge, this clinical trial was only the second in which FAW was used in patients without a commercial blanket. Kabbara and colleagues[18] utilised standard hospital

blankets and blew warm air between them. Similarly to Kabbara and colleagues, we also used the medium set temperature of 38 °C and no thermal injuries were reported. The design and size of commercial blankets is known to be associated with heat distribution[19], whereas it is not known how the heat is distributed inside the thermal suit. In small FAW blankets, heat is distributed more evenly, and therefore they are more efficient than larger blankets[20]. Conversely, the larger the area covered under the blanket the more effective is the warming. Inside the thermal suit, warm air can diffuse up to the upper body. This results in higher skin temperatures on the arm and chest, as seen in our study. Overall, the maximum skin temperatures remained below 37 °C in the Thermal suit group, which can be regarded as safe. The main disadvantage of the suit is the poor breathability that resulted in two patients sweating.

Prewarming is the most efficient method for preventing the decrease in core temperature caused by body heat redistribution after anaesthetic induction[21]. However, active prewarming was not implemented in our study due to a lack of resources and time, especially with the first patients of the day. Instead, we assumed the longer the thermal suit is worn preoperatively, the higher the core and peripheral temperatures on admission to the OR because a thermal suit is designed to prevent thermal loss[22]. Indeed, the Thermal suit group had higher peripheral temperatures on admission to the OR but there was no correlation with preoperative suit time. Still, the warmer periphery might account for the minor thermal redistribution in the Thermal suit group seen in the difference in the number of cases of intraoperative hypothermia (1 versus 6 patients). Ramanathan`s method for calculating mean skin temperatures was chosen to measure thermal redistribution since the method is non-invasive, simple and approved[23].

The incidence of hypothermia (core temperature < 36 °C) was only 5% in the Thermal suit group but 32% in the Hospital clothes group. Older age is a known risk factor for intraoperative hypothermia[24], as is a low preoperative normothermic baseline core temperature[25]. In our study, patients were on average younger than 70 years, and at the induction $Temp_{ZHF}$ was 37 (0.3) °C in the Thermal suit group and 36.9 (0.3) °C in the Hospital clothes group. Moreover, a cool ambient temperature and exposing the patient to surgery predispose to hypothermia[26]. The NICE guideline recommends that the ambient temperature be at least 21 °C while patients are exposed and that they should be adequately covered throughout the intraoperative phase[1]. Both these recommendations were accomplished in our study as the OR temperature was over 21 °C and a patient was covered except for the lateral side of chest, shoulder and upper arm.

The strengths of our study are the standard anaesthesia and type of surgery, allowing a similar area disposal for surgery and predictable duration of the procedure. Furthermore, the continuous core temperature monitoring with ZHF method is superior to bladder or oesophagus catheter methods, as it is non-invasive and indifferent to exact positioning or urine outflow. The standardisation of a patient BMI of between 25 and 40 was applied to permit more reliable results regarding the effect of the warming methods. However, this restriction made the enrolment of patients more difficult since 53 women were slender and failed to meet the inclusion criteria.

One limitation of our study is the choice of primary outcome, and consequently the resultant small sample size. The mean core temperature on admission to the recovery room has been applied as a primary outcome in several previous studies comparing various warming methods. Recently, however, intraoperative core temperature change and especially duration of hypothermia have been applied to assess the thermal condition or hypothermia burden of surgical patients[7].

Further, for the sample size calculation, we assumed a 0.5 °C difference in the mean core temperature between groups on admission to the recovery room, as was the case in the study by Janicki et al[15]. However, the actual difference was smaller (0.2 °C) and favoured the Hospital clothes group. In our study, we adhered to the NICE recommendations. However, had we allowed the core temperature to drop to 35.5 °C before enhancing warming, as was done in the study by Janicki et al, there might have been a bigger difference between groups favouring the Thermal suit group because the incidence of hypothermia was higher and the minimum $Temp_{ZHF}$ was lower in the Hospital clothes group.

Another limitation of the study is that we did not follow up on the use of the thermal suit for up to 24 hours. Although nearly all patients were satisfied with the suit, we know that some of them changed back to hospital clothes once in the ward since, despite our efforts, the suits were not always of an optimal size for the patient. The full benefits of the thermal suit may only be gained if the suit is worn from admission to discharge in this type of 24-hour in-hospital care. Further, the suit has an inner layer of fleece that is harmful to the environment, especially during washing[27]. Commercial FAW blankets, on the other hand, are single use, and waste is thus produced every time they are used. Moreover, the higher operating costs of thermal suit are not an advantage in hospital bids in which every cent is summed.

In the future, this new warming method should be studied in prewarming and during different types of surgeries in which exposed areas vary and the OR temperature has different demands. The breathability of the suit and the safety of the maximum set temperature should also be investigated. Moreover, the impact of body weight on the effect of these warming methods and perioperative heat balance should be studied in further clinical trials.

In conclusion, the thermal suit connected to the FAW unit was not found to be superior to the lower body FAW blanket and a warming mattress. Although the incidence of hypothermia was lower in the Thermal suit group, the mean core temperature did not differ between groups on admission to the recovery room. There was no difference in satisfaction of using thermal suit or hospital clothes, but the thermal suit costs are higher.

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Table 1 Patients` characteristics and perioperative data

	Thermal suit (n=20)	Hospital clothes (n=19)
Age (years)	66.7 (10.9)	62.3 (15.0)
Height (cm)	162 (7)	163 (7)
Weight (kg)	79 (10)	76 (11)
Body Mass Index (kg/m^2)	29.9 (3.2)	28.6 (3.4)
ASA class 1 / 2 / 3 (n)	1 / 16 / 3	3 /11 / 5
Order in OR I / II / III (n)	4 / 7 / 9	7 / 6 / 6
Preoperative waiting time depending on the order (h:min)	0:58 / 2:04 / 4:19	0:29 / 2:30 / 3:57
Duration of anaesthesia (h:min)	1:44 (0:17)	1:55 (0:22)
Duration of surgery (h:min)	1:17 (0:19)	1:24 (0:23)
Propofol (mg)	1066 (271)	1111 (333)
Remifentanil (µg)	701 (290)	744 (278)
Crystalloid (ml)	655 (202)	722 (207)

Estimated blood loss (ml)	25 (21)	24 (15)

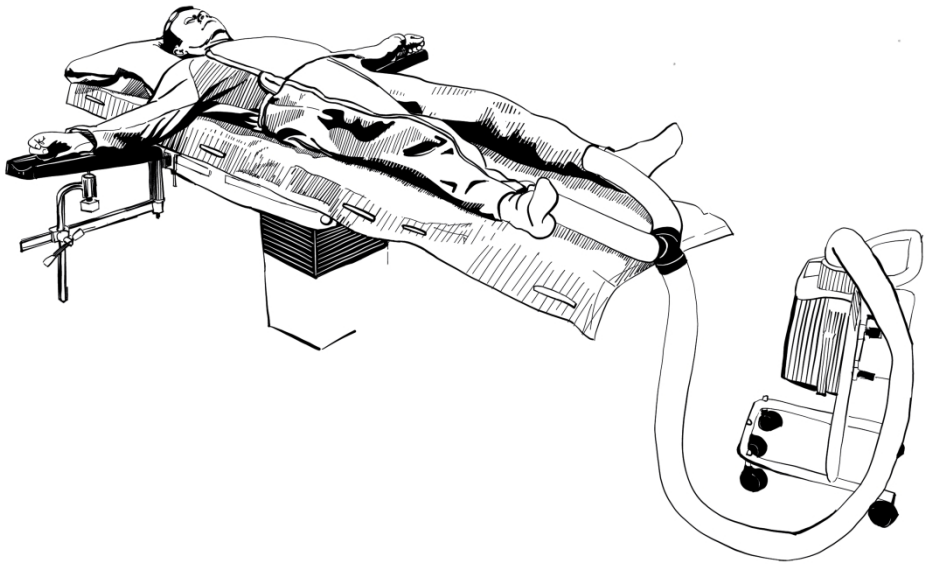
Footnote: values mean (SD) or number. ASA, American Society for Anesthesiologists. Order in OR (operating room): quantity of the patients being the first, second or third patient of the day in the operating room.

Table 2 Perioperative temperatures and incidence of inadvertent perioperative hypothermia

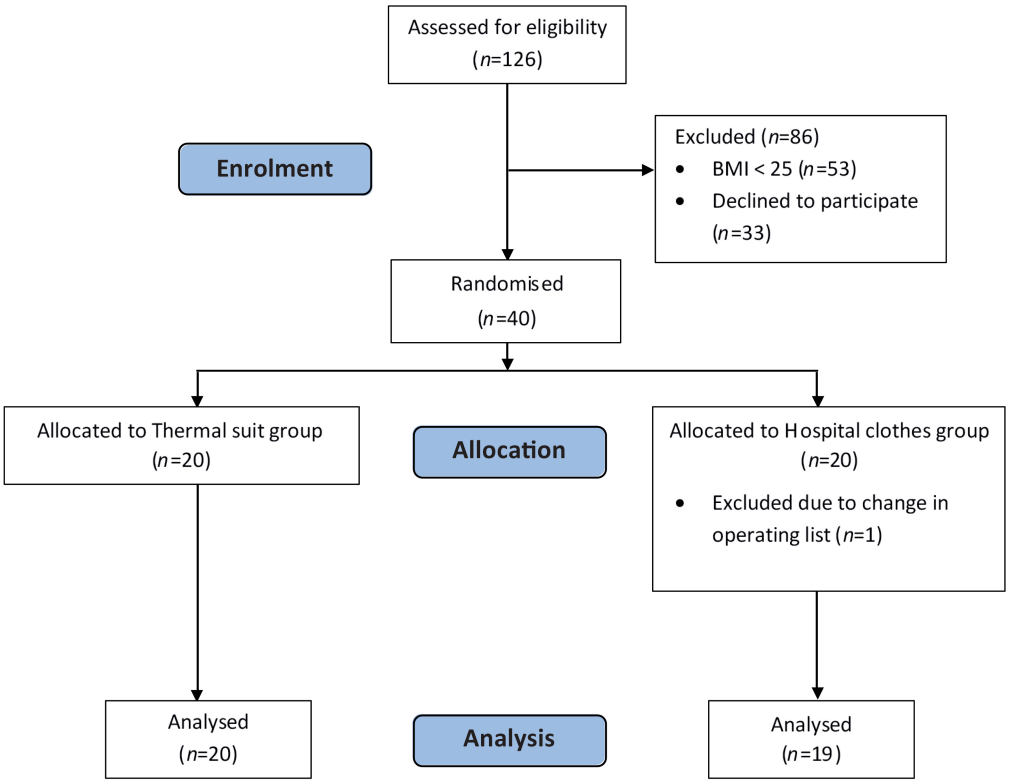
	Thermal suit (n=20)	Hospital clothes (n=19)	*P*-value
Preoperative eardrum temperature	36.5 (0.3)	36.3 (0.4)	0.08
Holding area temperature	23.0 (0.4)	23.1 (0.4)	0.67
Operating room temperature	21.9 (1.0)	21.8 (0.9)	0.93
$Temp_{ZHF}$			
Anaesthetic induction	37.0 (0.3)	36.9 (0.4)	0.44
End of anaesthesia	36.4 (0.3)	36.6 (0.3)	0.07
Admission to the recovery room	36.5 (0.4)	36.7 (0.3)	0.07
After 1 hour in the recovery room	36.7 (0.4)	36.8 (0.3)	0.20
Intraoperative skin temperatures			
chest (min-max)	35.1 (31.0 – 36.7)	34.5 (31.1 – 36.5)	0.03
arm (min-max)	33.9 (32.2 – 35.5)	33.0 (29.3 – 35.3)	< 0.00
thigh (min-max)	35.1 (29.8 – 36.7)	35.6 (30.3 – 38.0)	0.35
leg (min-max)	35.4 (31.1 – 36.7)	35.5 (31.2 – 38.0)	0.70

IPH intraoperatively	1 (5%)	6 (32%)	0.04
IPH on admission to the recovery room	1 (5%)	0 (0%)	0.33

Footnote: temperature (°C), values mean (SD) or number (proportion). IPH, inadvertent perioperative hypothermia (core temperature ≤ 35.9°C). $Temp_{ZHF}$, core temperature measured with zero-heat-flux sensor.



aas_13714_f1.jpg



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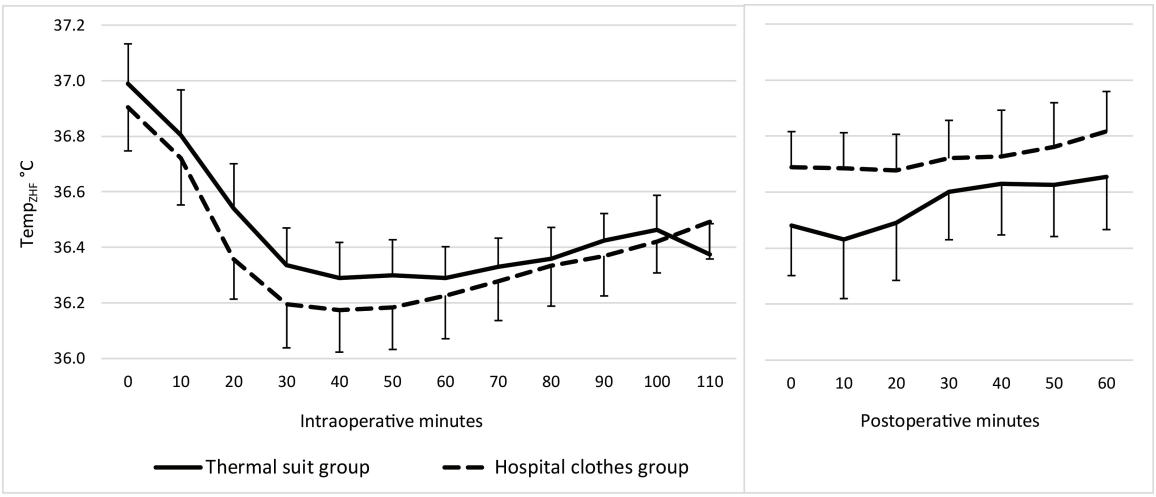

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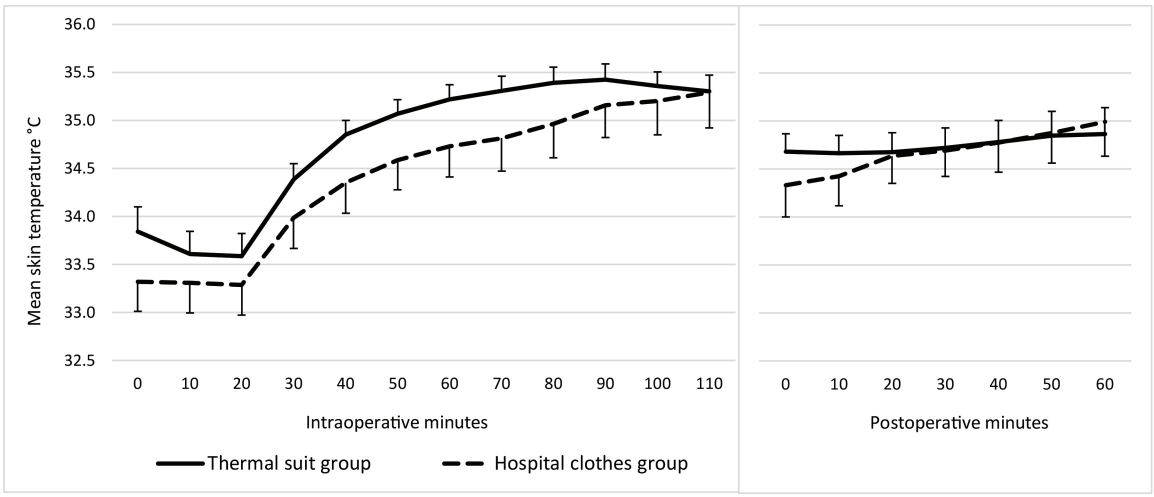

aas_13714_f4.jpg